

above cancellation of claims 6, 8, 9, 14-17, 20 and 21 the provisional Election is hereby affirmed. By the above cancellation of claims 3 and 10-13, Applicants' provisional Selection of Species is affirmed as well. Accordingly, these requirements are met.

Claims 1, 2, 4, 5, 7, 18 and 19 stand rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. In response, claims 1 and 2 have been amended to recite that the DNA is "isolated", as kindly suggested by the Examiner. Accordingly, this rejection is now overcome.

Claims 1, 2, 4, 5, 7, 18 and 19 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite for the reasons noted. In response, claims 1, 4 and 6 have been amended in order to delete "related to IgA nephropathy" or "nephropathy-related". Also, claims 1 and 2 have been amended to change "nucleotide sequences represented by SEQ ID NO: 1 to NO:32 and SEQ ID NO: 39 to NO: 42" to read --the group of nucleotide sequences consisting of SEQ ID NO: 1-6 and 9-12--. Accordingly, this rejection is now overcome as well.

Claims 1, 2, 4, 5, 7, 18 and 19 stand rejected under 35 U.S.C. §112, first paragraph, as failing to be supported by an enabling specification. In response, claim 1

has been amended¹ to specify what is intended by "stringent conditions". Accordingly, this rejection is also mooted.

In this regard, the Examiner will appreciate that the isolated DNA claimed herein relates to DNA whose expression level fluctuates in leukocytes of IgA nephropathy patients in comparison with leukocytes of healthy persons. Accordingly, such DNA would be reasonably expected by those of ordinary skill to be useful as a diagnostic marker or for specifying the target of a therapeutic agent.²

Claims 2, 7 and 19 stand rejected under 35 U.S.C. §102 as anticipated by the cited art for the reasons noted. In particular, these claims were rejected as anticipated by each of Adams et al., McKever, Krause et al, Gerken et al.,

1/ It is unclear to Applicants why claim 2 was so rejected since claim 2 does not recite the stringent condition terminology found objectionable by the Examiner. Clarification is respectfully requested.

2/ While the cause of IgA nephropathy is still unclear, it is considered that IgA production is excessive due to abnormality in the immune system, specifically in leukocytes such as in B cells relating to the production of IgA, and in T cells relating to regulation thereof. In the present invention, the expressed gene group fluctuates in leukocytes of IgA nephropathy patients, and it is therefore suggested that the genes are disease-related. Of course, DNAs which hybridize with the isolated DNAs (SEQ ID NO: 1-6 and 9-12) under stringent conditions are highly homologous and would be expected to have similar gene characteristics in expression property, function, and relationship to disease.

Stein et al., Podgorski et al., Takeda et al., Gantt, Lindr et al. and Soares et al. In this regard, the Examiner concludes each reference teaches sequences which might hybridize to SEQ ID NOS: 1-6 and 9-12, or an oligonucleotide stretch of at least 5 residues among the recited Sequence ID NOS. This is the sole remaining issue, the subject matter of SEQ ID NOS: 1-6 and 9-12 per se having been deemed allowable.

For the Examiner's convenience and to clarify the record, the overlapped DNAs between the present invention and the prior art cited are illustrated below.

"AACCTCTGCC TCCCAGGGTTC AAGTGATTCT CCTGCCT" (Adams et al., 1893-1931 of SEQ. ID NO. 1)
"CCCCAAAAAA AAAAAAAAAA AAAAAAAAAA AAAAAAAAAA AAAAA" (McEver, 2645-2689 of SEQ ID NO. 2)
"CACTGCAAGC TCCGCCTCCT GGGTTCACGC CATTCTCCTG CCTCAGCCTC CCA" (Kraus et al., 64-116 SEQ. ID NO. 3)
"TGGGCAACAG AGCAAGACCC AGTCTCA" (Gerken et al., 1416-1442 of SEQ ID NO: 4)
"GGGTTTCACT GTGTTAGCCA GGATGGTCTT GATCTCCTGA CCT" (Stein et al., 2567-2609 of SEQ ID NO. 5)
"CTTTATTTAA AAAAAAAAAA AAAAAAAAAA AAA" (Podgorski et al., 2244-2276 of SEQ ID NO. 6)
"AGAAGAAAGA GGGTC" (Takeda et al., 16-30 of SEQ ID NO. 9)
"AAAATATATA TATTGGTGCT G" (Gantt, 94-114 of SEQ ID NO. 10)
"TGACTTCTTT CAGAGGAC" (Linder et al., 30-47 of SEQ ID NO. 11)
"CTTATCCTGT AGCTATATAA CAGTTCATGT CTGATTAGC ATTTGTTCAC AGTAAAGCT
GGAACATGA AAATTGAAAA T" (Soares et al., 194-274 of SEQ ID NO. 12)

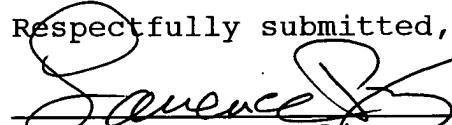
Initially, it will be appreciated that the foregoing sequences will not hybridize with the nucleotide sequences of SEQ ID NOS. 1-6 or 9-12 under the conditions now specified in claim 1. Moreover, the noted sequences are now specifically excluded by the amended language of claim 2. Accordingly, this rejection is overcome as well.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1, 2, 4-7, 18 and 19 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should be directed to our below listed address.

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